

Response 2 to Restriction Requirement
Application no. 10/790,386**Remarks**

The title of the invention is amended to reflect that the present claims are directed to a method. (certain composition claims for this invention having previously been granted).

The Examiner has required restriction between two groups of claims. Applicants have responded by electing to prosecute in the present application the claims of the second group, namely claims 13-23.

The Examiner has further required an election of species as to a single compound which is an MMPI and a single compound which is an estrogen or phytoestrogen. Applicants respectfully traverse the requirement.

Accordingly to the Manual of Patent Examining Procedure, "35 U.S.C. 121 provides that restriction may be required to one of two or more independent and distinct inventions. However, 37 CFR 1.141 provides that a reasonable number of species may still be claimed in one application if the other conditions of the rule are met." M.P.E.P. 806.04(a).

"Claims to be restricted to different species must be mutually exclusive. The general test as to when claims are restricted, respectively, to different species is the fact that one claim recites limitations which under the disclosure are found in a first species but not in a second, while a second claim recites limitations disclosed only for the second species and not the first. This is frequently expressed by saying that claims to be restricted to different species must recite the mutually exclusive characteristics of such species." M.P.E.P. 806.04(f)

Claims 13-23 which remain for examination following Applicants' response to the Restriction Requirement do not include any claims which recite a single compound. In fact, they don't contain any claims which recite a species of either the element (a) an MMPI or the element (b) an estrogen or phytoestrogen. Thus claims 13-23 do not contain any claims that are mutually exclusive as to different species. Accordingly, Applicants submit that their response to the Restriction Requirement was complete.

Nevertheless, in response to the Examiner's invitation and to expedite prosecution of the present application, Applicants herewith present additional claims 24 to 30 which recite compositions within the categories set forth in the claims as (a) and (b).

For purpose of provisional election of species, the recited MMPI is Ilomastat. The Examiner has requested Applicants to set forth the chemical structure of the elected species. From the U.S. Pharmacopeia:

Ilomastat [1994] (eye loe' ma stat'). C₂₀H₂₈N₄O₄. 388.46. (1) [*S*-(*R**,*S**)]-*N*'-Hydroxy-*N*'-[1*H*-indol-3-ylmethyl]-2-(methyl-amino)-2-oxoethyl]-2-(2-methylpropyl)butanediamide; (2) (*R*)-*N*'-Hydroxy-*N*'-[(*S*)-2-indol-3-yl-1-(methylcarbamoyl)ethyl]-2-isobutylsuccinamide. CAS-142880-36-2. INN. *Treatment of*

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corneal ulcers, inflammatory conditions, and cancers (matrix metalloproteinase inhibitor). (Baychem); (Raylo Chemicals, Canada))

For the purpose of provisional election of species, the recited "estrogen or phytoestrogen" is a plant extract comprising a triterpene glycoside. As disclosed in the specification at paragraph 0012 as published in US 2004/0185127 A1, such phytoestrogens can be extracted from the black cohosh plant, *Cimicifuga racemosa*. Further information may be found in the Shao reference cited in paragraph 0012 and, for further example, at U.S. Pharmacist on the Web at <http://tinyurl.com/bz6o7>

"Black cohosh (*Cimicifuga racemosa*), of the family Ranunculaceae, is a hardy perennial indigenous to the eastern U.S. but widely cultivated as an attractive garden ornamental. . . . The rhizomes and roots contain triterpene glycosides actein, cimicifugoside, and 27-deoxyactein, which are considered the main active constituents."

The Examiner's Action seems to require that each of the elected "species" be a "single compound," that is, a single molecular moiety. Applicants respectfully traverse the requirement. Applicants' disclosure teaches the use of plant extract comprising a triterpene glycoside, e.g. black cohosh extract, without requiring that a single chemical compound be separated out for the present use. Moreover Applicants call the Examiner's attention to the issued claims 2 to 4 in Applicants' U.S. patent 6,713,074 (the parent case of the present application) wherein similar recitations were allowed by the present Examiner in composition-of-matter claims. Applicants state that the recitation of "triterpenoid glycoside" in the aforesaid patent claims of the parent case mean the same as "triterpene glycoside" as stated in the specification of the parent case, the specification of the present case, and new claims 26 and 28 in the present amendment.

Claims 13 through 24 and 26 through 29, read on the provisionally elected species.

Applicants submit that the present response is complete and that the case is ready for substantive examination. However, if the Examiner wishes Applicants to address any other matters that would expedite prosecution, the Examiner is invited to phone Applicant's undersigned attorney.

Respectfully submitted:
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